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FluoroCouncil
Global Industry Council for FluoroTechnology

Dr. Meredith Williams
Deputy Director
Department of Toxic Substances Control (DTSC)
1001 "I" Street
P.O. Box 806
Sacramento, CA 95812
Submitted via online form at CalSAFER

Dear Dr. Williams:

FluoroCouncil appreciates this opportunity to provide comments on the CA DTSC Safer Consumer Products draft *Product – Chemical Profile for Perfluoroalkyl and Polyfluoroalkyl Substances (PFASs) in Carpets and Rugs* (hereafter "Chemical Profile"). FluoroCouncil is a global organization representing the world's leading manufacturers of products based on per- and polyfluoroalkyl substances (PFAS).[1] FluoroCouncil has a fundamental commitment to product stewardship and rigorous, science-based regulation, and, as part of its mission, addresses science and public policy issues related to PFAS.

PFAS is a term that describes a wide and diverse array of chemistry containing fluorine and carbon, including:

- Fluoropolymers (i.e., carbon-only polymer backbone with fluorines directly attached);
- Polymeric perfluoropolyethers (i.e., carbon and oxygen polymer backbone with fluorine directly attached to carbon backbone);
- Side chain fluorinated polymers (i.e., variable composition non-fluorinated polymer backbone with fluorinated side chains; includes both long and short chain fluorotelomer-based polymer products);
- Perfluoralkyl substances (i.e., non-polymeric compounds for which all hydrogen atoms on all carbon atoms (except for carbons which have been associated with functional groups) have been replaced by fluorine (includes both long and short chain)); and
- Polyfluoroalkyl substances (i.e., non-polymeric compounds for which all hydrogen atoms on at least one (but not all) carbon atom(s) - have been replaced by fluorine (includes both short-chain and long-chain)).

[1] FluoroCouncil's member companies are Archroma Management LLC, Arkema France, Asahi Glass Co., Ltd., Daikin Industries, Ltd., Solvay Specialty Polymers, The Chemours Company LLC, Dynax Corporation (associate), and Johnson Controls International plc. (associate).

Our review of the draft Chemical Profile has shown that it cannot appropriately be used to support the proposed designation of "PFASs in carpets and rugs" as a Priority Product under the Safer Consumer Products (SCP) regulations.[2] As discussed in more detail below, the document suffers from several major flaws that undermine its integrity and utility so significantly that the current draft Chemical Profile cannot be rehabilitated. DTSC should carefully consider the comments it receives and, based on those comments, issue a new draft Chemical Profile, if warranted.

First, the current draft Chemical Profile fails to reference a large body of data that was previously provided to DTSC that directly contradicts several of the key assumptions underpinning the current document. By ignoring this information, DTSC has deprived stakeholders of a meaningful opportunity to comment on the full body of data relevant to the proposed designation of "PFASs in carpets and rugs" as a Priority Product under the SCP regulations.

Second, the current draft Chemical Profile is legally insufficient to support the designation of "PFASs in carpets and rugs" as a Priority Product. This is due, in large part, to DTSC's inappropriate decision to list the entire universe of PFAS chemicals in carpets and rugs. Based on the criteria set forth in the SCP regulations, the proposed listing is unsupported, overbroad, and cannot be sustained.

Third, the best available scientific evidence demonstrates that the specific PFAS products that are actually used to treat carpets and rugs in the United States (US) will ***not*** cause substantial or widespread adverse impacts in California. These products have been carefully reviewed by the US Environmental Protection Agency (EPA), which maintains continuing regulatory oversight over the products. The overwhelming weight of scientific evidence supports the conclusion that these EPA-reviewed PFAS products do not meet the criteria for listing as a Priority Product under the SCP regulations. Therefore, if DTSC decides to proceed with a Priority Product designation for carpet and rug treatment products, those PFAS products that have been reviewed and approved by EPA should be excluded from the scope of that designation.

Finally, the draft Chemical Profile is replete with instances where DTSC has either misinterpreted or ignored the relevant scientific data and/or relied extensively and inappropriately on data that have no relevance to the products and chemistries that are actually used to treat carpets and rugs.

Given the depth and pervasiveness of these flaws, we believe that the current draft Chemical Profile document cannot be corrected. Therefore, we urge DTSC to withdraw the current document and start with a fresh analysis of the data.

We elaborate on our concerns in more detail below.

[2] California Code of Regulations Title 22, Division 4.5, Chapter 55.

I. The Draft Chemical Profile Ignores a Large Body of Previously-Submitted, Highly Relevant Data

Since DTSC first announced its intent to consider listing PFAS chemicals in carpeting as a Priority Product, FluoroCouncil has, on multiple occasions, provided DTSC with detailed information regarding the PFAS products that are used to treat carpets and rugs in the US.[3] This includes information identifying the types of PFAS substances comprising those carpet and rug treatment products, as well as information on the voluminous body of data elucidating the health, safety, and environmental characteristics of those substances. However, DTSC has largely ignored these data in assembling the draft Chemical Profile. As one example, a two-year carcinogenicity and chronic toxicity study pertaining to a chemistry that is actually used in carpeting is not discussed in the draft Chemical Profile, nor is it included in the document's list of references. However, this study is highly probative of the potential impacts associated with PFAS chemistries actually used in carpeting and, in fact, demonstrates that these chemistries do ***not*** present carcinogenicity or chronic toxicity concerns.[4]

Given the highly relevant nature of this information, it is difficult to understand why DTSC failed to discuss or reference these data in the draft Chemical Profile. DTSC's failure to consider and address this information clearly contravenes the public participation principles embodied in the SCP regulations, as well as the California Administrative Procedures Act (APA) and Office of Administrative Law (OAL) requirements.[5] Moreover, by failing to address or even reference highly probative and relevant information on these products, despite being aware of this information, DTSC has effectively deprived stakeholders of a meaningful opportunity to comment on the full body of data relevant to the proposed designation of "PFASs in carpets and rugs" as a Priority Product. This, too, contravenes the public participation principles embodied in the SCP regulations and the California APA and OAL requirements. DTSC's failure to address or reference highly probative information in its possession is a fatal flaw that renders the current draft Profile document grossly inaccurate and incapable of rehabilitation. If DTSC decides to proceed with a Priority Product designation for carpet and rug treatment products, the agency must start by re-issuing, and accepting public comment on, an accurate and transparent draft Chemical Profile.

[3] FluoroCouncil provided DTSC with such information during the DTSC's SCP Public Workshop on Perfluoroalkyl and Polyfluoroalkyl Substances (PFASs) in Carpets, Rugs, Indoor Upholstered Furniture, and Their Care and Treatment Products on January 31, 2017, and as follow-up to this workshop (in correspondence and in person). More recently, FluoroCouncil provided comments during DTSC's SCP Public Workshop on Perfluoroalkyl and Polyfluoroalkyl Substances (PFASs) in Carpets and Rugs on March 20, 2018.

[4] Klaunig, J.E., Shinohara, M., Iwai, H., Chengelis, C.P., Kirkpatrick, J.B., Wang, Z. and Bruner, R.H. 2015. Evaluation of the chronic toxicity and carcinogenicity of perfluorohexanoic acid (PFHxA) in Sprague-Dawley rats. Toxicol. Pathol. 43(2):209-220.

[5] California Code of Regulations, Chapter 3.5.

II. The Draft Chemical Profile is Legally Insufficient to Support the Designation of "PFASs in Carpets and Rugs" as a Priority Product

Under the SCP regulations, DTSC can designate a product-chemical combination to be a Priority Product only if the agency can show potential exposure to the Candidate Chemical contained in the product.[6] Thus, a substance that is not used or otherwise found in a product cannot be included in a Priority Product designation, as there can be no exposure to the substance "in the product." Accordingly, PFAS substances – or classes of PFAS substances – that are not used or present in carpets and rugs cannot be included in a Priority Product designation since there cannot be exposure to those substances from the products.

Only a small number of PFAS products – fewer than three dozen that we are aware of – are used to treat carpets in the US. Of the approximately 3,000 chemicals that comprise the universe of PFAS substances, the vast majority are not used and are not suitable for use in treating carpets. Fluoropolymers are one example of a class of PFAS chemicals that is not used in and is not suitable for use in treating carpeting. Yet, despite the fact that there is not and cannot be exposure to fluoropolymers from carpets and rugs, DTSC has included fluoropolymers within the scope of its proposed Priority Product designation, as outlined in the draft Chemical Profile.[7] This is just one example of the impermissible over-breadth of the proposed Priority Product listing that is the subject of the draft Chemical Profile.

In order to satisfy the "exposure" criterion in the regulations, DSTC's proposed Priority Product designation must focus on those substances that are actually present in carpets – including, specifically, the products that are used to treat carpets and rugs and the potential impurities or degradation products associated with those products. However, DTSC has made no effort in its draft Chemical Profile to identify and focus on the small subset of PFAS chemicals that are actually present, or may be present, in carpets and rugs. Because of this failure, the draft Chemical Profile is hopelessly overbroad, making meaningful comment on the document nearly impossible.

In addition to demonstrating exposure to the Candidate Chemical from the proposed product, the SCP regulations also require DTSC to show that exposure to the chemical from the product will cause or contribute to "significant" or "widespread" adverse impacts.[8] DTSC cannot make a showing of significant or widespread adverse impacts for the entire universe of PFAS chemicals. Again, fluoropolymers are one example that illustrates the larger point. The overwhelming

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[6] California Code of Regulations Title 22, Division 4.5, Chapter 55 § 69503.2(a)(1); *see also* § 69503.2(b)(1)(A); ("The Department shall begin the product-chemical combination evaluation process by evaluating the potential adverse impacts posed by the Candidate Chemical(s) ***in the product*** due to potential exposures during the life cycle of the product.") (emphasis added).

[7] It appears that DTSC decided to address fluoropolymers in the Chemical Profile on the basis of a single patent application that suggested that fluoropolymers might be used in carpeting treatments. However, beyond this one statement in a patent filing, there is ***no*** evidence that fluoropolymers have ever been used to treat carpets or rugs or that they are suitable for such use. Indeed, the Carpet and Rug Institute has confirmed that fluoropolymers are not used in this application.

[8] California Code of Regulations Title 22, Division 4.5, Chapter 55 §69503.2(a)(2).

weight of scientific evidence demonstrates that fluoropolymers – which satisfy the OECD criteria for "polymers of low concern" – are chemically and biologically inert and, therefore, do not present relevant health or environmental risks.[9] As such, there is no basis for DTSC to conclude that fluoropolymers cause or contribute to significant or widespread adverse impacts. Therefore, a finding of "substantial or widespread adverse impacts" cannot be made for the entire universe of PFAS chemicals. Again, this is just one example of the impermissible over-breadth of the draft Chemical Profile's proposed Priority Product listing of "all PFASs" in carpets and rugs.

III. PFAS Substances That Are Used to Treat Carpets and Rugs in the US Do Not Meet the Criteria for Designation as a Priority Product

Information previously supplied to DTSC demonstrates that the vast majority of PFAS chemicals that are actually used to treat carpets and rugs in the US are side-chain fluorinated polymers and, more specifically, short-chain side-chain polymers (i.e., polyfluoroalkyl polymers with fluorinated side chains containing six or fewer carbons). In particular, the carpet and rug treatment products manufactured and marketed by FluoroCouncil member companies are short-chain side-chain acrylate- or methacrylate-based polymers with fluorinated carboxylate chains of six carbon atoms (referred to here as "C6" chemistry).

FluoroCouncil member companies have generated a large body of data demonstrating the safety of C6-based chemicals. These data, which have previously been provided to DTSC, but were largely ignored in the draft Chemical Profile, demonstrate that C6-based side-chain polymers and their primary degradation products are not carcinogenic, are not mutagenic, are not neurotoxic, and are not reproductive toxins. It is difficult to understand why these data were not discussed at any length – or at all – in the draft Chemical Profile, even though they are arguably the most relevant data available on those PFAS products that are ***actually used*** to treat carpets and rugs in the US.

With respect to the safety of C6 side-chain polymers, it is important to recognize that the polymers themselves are high molecular weight molecules that are not bioavailable; therefore, they do not present toxicity concerns. As DTSC itself acknowledges in its draft Chemical Profile, to the extent that side-chain polymers may be associated with adverse impacts, those impacts are primarily associated with the perfluoroalkyl acids that could theoretically result from degradation of the polymers. More specifically, in the case of C6-based side-chain polymers, the primary degradant of potential concern is perfluorohexanoic acid (PFHxA). However, as discussed above, FluoroCouncil has provided DTSC with a large volume of data demonstrating that PFHxA is not associated with any significant adverse health or safety impacts. Moreover, FluoroCouncil has informed DTSC of a recently completed, long-term biodegradation study demonstrating that C6 side-chain polymers do not degrade under environmentally relevant conditions. Specifically, the study, which was conducted using EPA-approved protocols and

[9] Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J., and Hernandez, O. 2018. A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers. Integr Environ Assess Manag 9999:1-19 (available open access at https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035).

following EPA-imposed Good Laboratory Practice standards (GLPs), demonstrates that C6-based side-chain polymers have an environmental half-life in the ***thousands*** of years[10].

Thus, the best available scientific evidence indicates that C6-based side-chain polymers do not degrade in any meaningful way under environmentally relevant conditions, which means that potential exposure to theoretical degradation products will be negligible. Moreover, a large body of scientific evidence indicates that the primary degradation products associated with C6-based side-chain polymers do not present significant adverse health or safety impacts. This information, which is largely absent from the draft Chemical Profile, demonstrates that C6-based side-chain polymers – which are the primary carpet treatment products in use today – do ***not*** present significant or widespread adverse impacts.

IV. The Draft Chemical Profile is Fundamentally Flawed from Both a Factual and Scientific Basis, and Its Conclusions Are Based on Incomplete Information as Well as Erroneous and Unsupported Assumptions

As already discussed, the draft Chemical Profile fails to address the PFAS products that are actually used to treat carpets and rugs in the US and ignores the most relevant data pertaining to those products. Instead, the document focuses on PFAS chemicals that are not used to treat carpets and rugs in the US. In fact, none of the PFAS compounds that are the focus of most of DTSC's hazard or exposure evaluations are present in carpets and rugs. Rather than concentrating on short-chain side-chain fluorinated polymers – which comprise the vast majority of PFAS chemicals used to treat carpet and rugs in the US – the analysis contained in the draft Chemical Profile is largely centered on nonpolymer long-chain PFAS chemicals, PFOA and PFOS, which are improperly used to infer risks from exposure to unrelated PFAS products in carpets and rugs. This approach is scientifically unsound, inappropriate, and misleading.

Our remaining comments are divided into two parts. First, we highlight some of the fundamental errors and inaccuracies in the draft Chemical Profile related to the generalization of data specific to long-chain nonpolymeric PFAS chemicals across all PFAS subclasses. Second, we discuss specific toxicological and exposure information related to the of short-chain nonpolymeric PFAS that could hypothetically result from degradation of the side-chain fluorinated polymers that are actually used in carpet and rug treatments in the US today. These data demonstrate that there is negligible risk to human health or the environment from ***all*** potential routes of exposure to short-chain nonpolymeric PFAS (e.g. PFHxA, PFBA).

A. Inaccuracies and Inappropriate Assumptions in the Draft Chemical Profile

Given the high number of factually incorrect and/or inaccurate statements throughout the document, the following comments represent only a few examples of the corrections that are needed to remedy these statements; they should be applied where applicable throughout the draft Chemical Profile. These comments highlight the need for a much more precise evaluation of relevant data, consistent with the requirements of the SCP regulations, as well as the California APA and OAL requirements.

[10] NuvaRP2116 GA 39/13-1 -Aerobic Transformation in Soil study conducted under OECD 307 by Noack Laboratory GmbH (November 1, 2017). Submitted to U.S. EPA by Archroma U.S. Inc. on November 11, 2017.

1. Summary, (p. 5, second paragraph) states, "DTSC has identified carpets and rugs as sources of significant widespread human and ecological PFAS exposures." This statement has no citations and needs to be specific to the side-chain fluorinated polymers used in carpet and rug surface treatments. FluoroCouncil is unaware of any data demonstrating widespread human or ecological exposures to C6-based side-chain fluorinated acrylate and methacrylate polymers.
2. Summary, (p. 5, third paragraph) states, "…PFASs released to the environment end up virtually everywhere in aquatic, atmospheric, and terrestrial environments…" Additionally, Summary, fourth paragraph (p. 5) states, "Carpets and rugs contribute to the widespread environmental contamination and exposures…" Similar language also appears in the text box on page 5. FluoroCouncil is unaware of any data demonstrating widespread environmental occurrence of fluorinated acrylate or methacrylate side-chain polymers polymers – despite the fact that they have been in commerce in the US for more than a decade. Side-chain acrylate and methacrylate polymers are not water-soluble and, therefore, not mobile in water. They are also not volatile and, therefore, not subject to atmospheric transport.
3. Summary, (p. 5, fourth paragraph) states, "Because persistent PFASs lack a natural degradation route, their levels in the environment, humans and biota may continue to rise for as long as PFASs are produced and used in consumer products." This statement is incorrect for PFAS that are not bioavailable and for PFAS that do not bioaccumulate, such as side-chain fluorinated acrylate and methacrylate polymers. For these subclasses of PFAS, including C6-based side-chain polymers, persistence in the environment would not contribute to increasing levels in humans.
4. Summary (p. 6, throughout paragraphs one through three). Statements herein are factually incorrect when applied to all PFAS without a clear and accurate distinction between polymer PFAS, non-polymer PFAS, and other subclasses. Statements specific to long-chain non-polymer PFAS are not relevant to the evaluation of short-chain acrylate and methacrylate side-chain polymers, which are ***actually used*** in carpet or rug surface treatment. Therefore, these statements should be removed from the draft Chemical Profile.
5. Summary (p. 6, fourth paragraph). This paragraph generalizes data specific only for PFOA and PFOS. Given that these two specific non-polymer PFAS are not associated with the manufacture, use, or degradation of short-chain fluorinated acrylate or methacrylate polymers used in carpet treatment products in the US, these statements should be removed for accuracy.[11]
6. Summary, (p. 6, fifth paragraph) discusses non-polymer long-chain PFAS and fluorinated ethers, which are not associated with the manufacture, use, or degradation

[11] Moreover, DTSC should recognize that regulations promulgated by EPA pursuant to Section 5 of TSCA prohibit the use of long chain PFAS chemicals in carpet treatment products, as well as the importation of carpets that have been treated with long chain compounds. *See* 78 Fed Reg 62443 (Oct. 22, 2013). Since only long chain products degrade to PFOA and PFOS, and since these long chain products cannot lawfully be used in carpets in the US, DTSC's use of PFOA and PFOS data to justify its proposed Priority Product designation is misplaced and inappropriate, particularly in light of the SCP regulations at Chapter 55 §69503.2(a)(3).

of side-chain fluorinated acrylate or methacrylate polymers. These statements should be removed for accuracy.

7. Section 1.1 - Scope of Candidate Chemical (p. 8). As discussed previously, DTSC's proposed designation of all PFAS chemicals in carpets and rugs as a Priority Product is impermissibly overbroad and inconsistent with the SCP regulations. Although all PFAS are Candidate Chemicals under the SCP Program, the vast majority of PFAS are not associated with, or even suitable for, carpet and/or rug treatment. Moreover, there are clear distinctions between polymeric and non-polymeric PFAS and between long-chain non-polymer PFAS and short-chain non-polymer PFAS that preclude read-across from these major subclasses.

8. Section 1.1 - Scope of Candidate Chemical (pp. 8-9) and Section 1.3 - Chemical Product Use and Trends (p. 12). As previously discussed, the vast majority of PFAS used for carpet and rug treatment in the US consists of short-chain fluorinated acrylate or methacrylate side-chain polymers. The Chemical Profile should focus on these specific PFAS and any related non-polymer PFAS that may be associated with use, degradation, and/or disposal. In particular, DTSC should acknowledge the large body of scientific data supporting the safety of these short chain substances. In addition, DTSC must consider data from a long-term study recently submitted to EPA that demonstrates that C6-based side chain polymers have an environmental half-life in the ***thousands*** of years.[12]

15- Month OECD 307 Aerobic Soil Study on C6 Side-Chain Polymers:

- GLP study
- EPA-approved protocols
- Very low potential for aerobic biological transformation
- Calculated half-lives of the polymer were between 3,000 to 5,500 years depending on soil type

9. Section 1.3 - Chemical Product Use and Trends (p.13, first paragraph) states, "However, other polymeric PFASs such as PFPEs, and fluoropolymers may also be used," and cites a January 2013 patent from Iverson, et al. (2017) that mentions PFPEs. A patent does not indicate or reflect actual commercial use of a product. As far as we are aware, PFPEs have not been able to provide effective stain-resistance for carpet or rug treatments and are not on the US market for this product use.

10. Section 2.1 - Physicochemical Properties (p. 14) should focus on short-chain side-chain fluorinated acrylate and methacrylate polymers and related potential impurities or degradation products.

11. Section 2.1 - Physicochemical Properties (p. 15, text box) states, "PFASs are proteinophillic (protein-binding), accumulating particularly in blood, liver, stomach, kidneys, lungs, gall bladder, brain, muscle, and yolk sac tissues." This statement is factually incorrect. Polymeric PFAS such as side-chain fluorinated methacrylate polymers are not bioavailable due to their high molecular weight.

[12] NuvaRP2116 GA 39/13-1 -Aerobic Transformation in Soil study conducted under OECD 307 by Noack Laboratory GmbH (November 1, 2017). Submitted to U.S. EPA by Archroma U.S. Inc. on November 11, 2017.

12. Section 2.2 - Environmental Fate and Transport (p. 19) should focus on short-chain side-chain fluorinated acrylate and methacrylate polymers and related potential impurities or degradation products.

13. Section 2.2.2 should focus on side-chain fluorinated acrylate and methacrylate polymers and related potential impurities or degradation products. As mentioned previously, regulations promulgated by EPA pursuant to TSCA prohibit the use of long-chain PFAS chemicals in carpet treatment products in the US, as well as the importation of carpets that have been treated with long-chain compounds. The mention of fluorotelomer-based side-chain fluorinated polymers that can degrade into fluorotelomers (FTOHs) with short-chain perfluorocarboxylic substances (PFCAs) as terminal degradation products (Washington et al. 2015) is correct, up to a point. As discussed previously, a long-term study recently submitted to EPA demonstrates that C6-based side chain polymers have an environmental half-life in the ***thousands*** of years. Similar comments can be made for Section 2.3, 2.4, 2.5, 3.2, 3.3 and others.

14. Section 2.4. The potential effects related to exposure to a mixture of chemicals requires either dose-additivity or response-additivity (U.S. EPA 2007). Thus far, there is no indication that C6-based side-chain fluorinated polymers would have any dose- or response-additivity with long-chain nonpolymeric PFAS.

15. Sections 2.5 3.2, and 3.3. Polymers are generally considered non-bioavailable and not biologically reactive. Furthermore, side-chain fluorinated polymers have not been shown to be widespread in the environment; they are not water soluble and not subject to long-range transport.

16. Section 5 should focus on side-chain fluorinated acrylate and methacrylate polymers and related potential impurities or degradation products. It is misleading, factually incorrect, and scientifically unsound to associate or ascribe potential health risks related to PFOA and PFOS to C6-based carpet and rug treatments currently used within the US.

17. Section 5.2 - Key Data Gaps (p. 58, fourth paragraph) states, "Toxicological data are limited to a few PFASs – mostly longer-chain PFAAs such as PFOA and PFOS." This is incorrect. As discussed in further detail in Section B, below, there are a sufficient number of toxicological studies available on the potentially relevant short-chain nonpolymeric PFAS, such as PFHxA and PFBA, to derive human health-based toxicity values and to assess the potential human health risk.

18. Section 6.2. It is factually incorrect to state that PFAS associated with carpets and rugs show evidence for carcinogenicity, developmental toxicity, reproductive toxicity, etc., as this list of toxicological endpoints have ***not*** been associated with C6-based fluorinated acrylate and methacrylate polymers or their degradation products.

19. Section 6.3. Neither polymeric PFAS, including C6-based fluorinated acrylate and methacrylate polymers, nor their degradation products or manufacturing impurities have shown terrestrial ecotoxicity or aquatic toxicity at levels found in the environment.

B. Exposure and Toxicological Information Pertinent to Hypothetical Degradation Products and Impurities of Short-Chain Side-Chain Fluorinated Polymers

Side-chain fluorinated polymers are extremely stable, not bioavailable, and not biologically active (OECD 1993, USEPA 1997). Furthermore, given the completely distinct chemical properties for polymer versus nonpolymeric PFAS, it is neither appropriate nor factually correct to generalize data across these major classes. Of course, it is possible that trace levels of short-chain carboxylates (e.g., PFHxA and PFBA) might be present as impurities in the manufacturing processes for the side-chain polymers. Additionally, with a half-life in the thousands of years, it is hypothetically possible that side-chain fluorinated polymers could degrade into PFHxA or PFBA. However, as summarized below, the collective toxicology evidence indicates low hazards and a high margin of safety for PFBA and PFHxA from all potential sources and routes of exposure. While both PFBA and PFHxA are persistent in the environment, toxicity bioassays demonstrate low toxicity profiles including only moderate and often reversible treatment-related effects, even at the high doses administered in repeat-dose animal studies. PFBA and PFHxA are rapidly excreted from both rodent and human serums, indicating that no additional kinetic factor is necessary to account for species-specific bioaccumulation, and standard allometric scaling based on body weight is appropriate. Toxicological databases for both chemicals are sufficient for derivation of human health-based thresholds (e.g., ANSES 2017), and the use of standard "uncertainty factors" in risk assessments ensure that remaining data gaps and/or uncertainties are adequately accounted for.

Hazard Profile for Side-Chain Fluorotelomer-based PFAS

- Highly stable (1,000+ years)
- Not bioavailable
- Low hazard based on potential degradation products or impurities (e.g., PFHxA)

PFHxA:

The full suite of standard laboratory assays are available for PFHxA and include: a 2 year rodent cancer bioassay (Klaunig et al. 2015); DNA mutation and genotoxicity in vitro assays (NTP 2018; Loveless et al. 2009; Eriksen et al. 2010); chronic systemic toxicity rodent bioassay (Klaunig et al. 2015); reproductive/developmental rodent bioassays (Loveless et al. 2009; Iwai and Hoberman 2014); subchronic systemic toxicity bioassays (Loveless et al. 2009, Chengelis et al. 2009a; Iwai and Hoberman 2014); analysis of endocrine disruption (Borghoff in press, presented as poster at SETAC North America 2017); high-throughput molecular *in vitro* assays (EPA Tox21); and toxicokinetic assays in rats, mice, microminipigs, monkeys, and humans (many, examples include Chengelis et al. 2009b; Iwai and Hoberman 2014; Russell et al. 2013, 2015; Nilsson et al. 2010, 2013; Fujii et al. 2015; Guruge et al. 2016; Gannon et al. 2011, 2016).

PFHxA was not carcinogenic and has not exhibited any DNA mutation or genotoxic effects in several studies (NTP 2018; Klaunig et al. 2015; Loveless et al. 2009). A

comprehensive review of both *in vitro* and *in vivo* studies evaluating PFHxA activity across endocrine pathways shows that PFHxA is not bioactive in estrogen, androgen, aromatase, or thyroid receptor signaling pathways (Borghoff in prep.). Effects noted from high level exposure to PFHxA in subchronic and chronic noncancer rodent bioassays include liver, thyroid, kidney, and hematologic effects (Loveless et al. 2009; Chengelis et al. 2009a; Iwai and Hoberman 2014), with the lowest no-observed-adverse-effects level (NOAEL) of 30 mg/kg-day from the chronic rat study (Klaunig et al. 2015). In animal studies, PFHxA does not exhibit adverse effects on reproduction, and developmental effects are highly uncertain and only occur at higher doses than other endpoints.

There are very few human observational studies that have included PFHxA due to the low frequency of detection and low levels detected. A study of Taiwanese children found no association with PFHxA and immunological markers or asthma in the children (Dong et al. 2013). A study of the general population in China found that exposure to PFHxA was positively associated with two thyroid antibody markers often used as clinical markers for thyroid autoimmune diseases (Li et al. 2017); however, this was inconsistent with the other PFAS included in the study (i.e., PFOS, PFHxS, PFOA, PFBS) and is inconsistent with the rat studies of thyroid effects (Loveless et al. 2009).

PFHxA Human Health Toxicity Value is 16,000 x less stringent than PFOA

	RfD mg/kg-d	Agency (year)
PFHxA	0.32	USEPA (2016)
PFOA	0.00002	ANSES (2017)

The French National Agency for Food Safety, Environment and Labor (ANSES) has also recently derived a reference dose for PFHxA. The agency concluded that the kidney effects from Klaunig et al. (2015) were severe enough to be considered adverse and would also be protective of other potential effects. A PFHxA toxicity value of 0.32 mg/kg-day was derived based on the NOAEL of 30 mg/kg-day (Klaunig et al. 2015), standard allometric scaling based on body weight ratios to derive the human equivalent dose, and application of uncertainty factors for interspecies variability (2.5) and inter-individual variability (10) (ANSES 2017).

PFBA:

The standard laboratory assays available for PFBA include: subacute (28-day) oral toxicity tests in rodents (Foreman et al. 2009; Butenhoff et al. 2012); subchronic (90-day) oral toxicity tests in rodents (Butenhoff et al. 2012); developmental toxicity assay (GD1-17 in mice) (Das et al. 2008); toxicokinetic studies in mice, rats, monkeys, and humans (Chang et al. 2008); and numerous *in vitro* and high-throughput screening assays.

From these studies, the standard suite of noncancer endpoints has been evaluated, including overt toxicity, gross neurological effects (functional observational battery tests), body weight changes, organ weights and histopathology, and hematology parameters. The three subchronic animal bioassays all demonstrate mild toxicity with questionable adversity and signs of reversibility. The PFBA toxicological database is missing chronic noncancer, multigenerational reproductive and developmental studies.

Given the rapid elimination rate of PFBA (~75 hour elimination half-life in humans [Chang et al. 2008]), the subchronic studies are sufficient to establish pseudo-steady state tissue concentrations in test animals. It is unclear if longer exposure durations would result in different study findings; however, this is expected to be a low source of uncertainty in the characterization of hazard profiles. A chronic cancer bioassay for PFBA has also not been conducted. However, none of the short-chain PFAAs have shown any carcinogenic potential.

ANSES recently derived a reference dose for PFBA. The agency selected liver effects (statistically significant increase in absolute and relative liver weight and hepatocellular hypertrophy) noted in Butenhoff, et al. (2012) for the derivation of their toxicity value due to clear hepatotoxicity associated with exposure to related PFAA compounds and noted hepatic effects following PFBA in other studies. A PFBA toxicity value of 0.024 mg/kg-day was derived based on the NOAEL of 6 mg/kg-day (Butenhoff et al. 2012), standard allometric scaling based on body weight ratios to derive the human equivalent dose, and application of uncertainty factors for interspecies variability (2.5), inter-individual variability (10), and subchronic to chronic extrapolation uncertainty (3) (ANSES 2017).

Cumulative Exposures To Short-Chain Perfluorocarboxylates Are Extremely Low:

The available data consistently show extremely low frequencies of detections and low levels of detection for PFHxA in both environmental media and in the human population.

PFHxA and PFBA are environmentally persistent, water soluble, and have been found in drinking water in several countries (Jian 2017, ATSDR 2015). Data gaps regarding the levels of PFHxA in the environment and human serum exist because PFHxA has generally been excluded by environmental monitoring surveys and blood serum analyses due to the low frequency of detection and low levels of detection compared to the associated method detection limit. This is the stated reason why PFHxA was not included in the US EPA's Unregulated Contaminant Monitoring Rule evaluation or the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey (NHANES). Other biomonitoring surveys consistently demonstrate that PFHxA is infrequently detected in human serum, particularly compared with most other perfluoroalkyl acids.

Thus far, the empirical data on the potential cumulative exposure to PFBA or PFHxA in the environment, in human serum from biomonitoring studies, and data from standard laboratory animal bioassays all support a conclusion that if present in trace amounts as impurities or degradation products from the specific polymeric PFAS used in carpet and rug products, PFBA and PFHxA pose no human health risk based on standard risk assessment methodology.

Conclusion

The draft Chemical Profile suffers from a number of major flaws that significantly undermine the integrity and utility of the document. The document fails to address highly probative data that DTSC is aware of, does not consider all relevant and appropriate information, and is impermissibly overbroad. Because of the severity and pervasiveness of these flaws, stakeholders have been deprived of the opportunity to provide meaningful comments on the full body of data relevant to the proposed designation of "PFASs in carpets and rugs" as a Priority Product. As a result of these fundamental deficiencies, the current draft Chemical Profile cannot be rehabilitated. DTSC should carefully consider the comments it receives and, based on those comments, should issue a new draft profile document, if warranted.

Moreover, the overwhelming weight of scientific evidence demonstrates that the specific PFAS products that are ***actually used*** to treat carpets and rugs in the US – C6-based side-chain fluorinated acrylate and methacrylate polymers – will not cause substantial or widespread adverse impacts in California and do not meet the criteria for listing as a Priority Product under the SCP regulations. Therefore, if DTSC decides to proceed with a Priority Product designation for carpet and rug treatment products, these C6-based side-chain polymer products – which have been carefully reviewed and strictly regulated by EPA – should be excluded from the scope of any future Priority Product designation.

Thank you for the opportunity to provide comments on the draft Chemical Profile. We look forward to further discussing PFAS chemistry and the FluoroCouncil's commitments to stewardship. Please contact me at 202-249-6737 or jessica_bowman@fluorocouncil.org with any questions.

Sincerely,

Jessica S. Bowman
Executive Director